

73049-65

2/11/2014

1/s

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

FEB 11 2014

Ms. Jayne Walz  
Regulatory Manager  
Valent BioSciences Corporation  
870 Technology Way  
Libertyville, IL 60048-6316

Re: Valent BioSciences Corporation; *Bacillus sphaericus* Slurry  
EPA Registration No. 73049-65  
Minor Label and Formulation ("Fast Track") Amendment  
Submissions Dated 04/04/2011, 10/29/2013, 01/31/2014, and 02/07/2014  
Decision No. 448007

Dear Ms. Walz:

The U.S. Environmental Protection Agency (EPA) reviewed your request to amend the subject product registration, which included the following changes to the product label:

- 1) Correction of minor formatting inconsistencies and typographical errors.
- 2) Addition of "Registrant" in front of Valent BioSciences Corporation's name and address and addition of AbbVie, Inc.'s name and address (preceded by "Manufactured by:") in accordance with 40 CFR § 156.10(c).
- 3) Modification of the dust mask statement in the Hazards to Humans and Domestic Animals section.
- 4) Modification of the Hot Line Number in the First Aid box.
- 5) Addition of more specific use sites (for end-use pesticide products to be formulated from this pesticide product) in the Directions for Use.
- 6) Addition of the following statement to the Container Handling section of the Storage and Disposal box: "If burned, stay out of smoke."

CONCURRENCES

MBOL	7511P	7511P	7511P				
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DATE	02/10/2014	2/11/14	2/11/14				

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Jayne Walz  
EPA Registration No. 73049-65

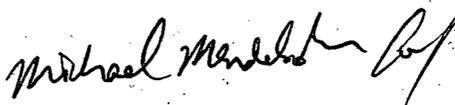
Additionally, you updated the confidential statement of formula (CSF) on file for *Bacillus sphaericus* Slurry. There is now only one valid CSF for this product registration: a basic formulation dated October 20, 2013. All previously accepted *Bacillus sphaericus* Slurry CSFs have been superseded by the aforementioned CSF.

All the changes referred to above, submitted in connection with registration under section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), are acceptable provided that you submit two (2) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for further description of final printed labeling.

Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions. If you have any questions regarding this letter, please contact Ms. Jeannine Kausch by telephone (703-347-8920) or email ([kausch.jeannine@epa.gov](mailto:kausch.jeannine@epa.gov)).

A stamped copy of the label is enclosed for your records.

Sincerely,



Kimberly Nesci, Chief  
Microbial Pesticides Branch  
Biopesticides and Pollution  
Prevention Division (7511P)

Enclosures (2):

- *Bacillus sphaericus* Slurry Stamped, Accepted Label
- A-79 Enclosure

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**Bacillus sphaericus Slurry**

BIOLOGICAL INSECTICIDE

FOR MANUFACTURING USE ONLY

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

**ACTIVE INGREDIENT:**

*Bacillus sphaericus* 2362, serotype H5a5b, strain ABTS 1743 fermentation

solids, spores and insecticidal toxins..... 11.0% w/w

OTHER INGREDIENTS..... 89.0% w/w

Total: 100.0% w/w

**The % active ingredient does not indicate product performance**

EPA Registration No. 73049-65

Lot No: \_\_\_\_\_

EPA Establishment No.

Registrant/Manufactured for: Valent BioSciences Corporation

870 Technology Way  
Libertyville, IL 60048  
1-800-323-9597

**ACCEPTED**  
FEB 11 2014

Manufactured by: AbbVie, Inc.  
1401 Sheridan Road  
North Chicago, IL 60064

Under the Federal Insecticide, Fungicide,  
and Rodenticide Act, as amended, for  
the pesticide registered under  
EPA Reg. No. 73049-65

Net Contents:

**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**CAUTION**

Harmful if absorbed through the skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

When handling this product, wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.

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<b>FIRST AID</b>	
<b>If on skin or clothing:</b>	<ul style="list-style-type: none"><li>• Take off contaminated clothing.</li><li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
<b>If in eyes:</b>	<ul style="list-style-type: none"><li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li><li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li><li>• Call a poison control center or doctor for treatment.</li></ul>
<b>HOT LINE NUMBER</b>	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-877-315-9819 (24 hours) for emergency medical treatment and/or transportation emergency information. For all other information, call 1-800-323-9597.	

### **ENVIRONMENTAL HAZARDS**

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This slurry is intended for formulation into insecticidal products for use on food and non-food crops in agricultural areas and in areas where no crops are grown.

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## **STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by storage and disposal.

### **PESTICIDE STORAGE:**

Store in cool, dry conditions.

### **PESTICIDE DISPOSAL:**

Wastes resulting from the use of this product must be disposed of on-site or at an approved waste disposal facility.

### **CONTAINER HANDLING:**

Nonrefillable container. Do not reuse or refill this container. Triple rinse (or equivalent). Then offer for recycling if available, or puncture and dispose of in a sanitary landfill or by incineration. Do not burn, unless allowed by state and local ordinances. If burned stay out of smoke.

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